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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,898	04/15/2004	William J. Boyle	A-451K	8965

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,898	BOYLE, WILLIAM J.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 58-70 is/are pending in the application.

4a) Of the above claim(s) 69 and 70 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 58-68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 4/15/04 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of the species elected for A)-C) in the reply filed on 6/8/07 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicant comments, the claimed methods are distinct for the reasons elaborated in the previous Office Action and because the method of the previously pending claims recited a method for detection of mutually exclusive compounds (aka agonists versus antagonists). Regarding applicants comments, applicant has elected the test compound of previously pending claim 48 (an antibody), wherein the agents of claims 69 /70 are not antibodies and are therefore drawn to nonelected species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 69/70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/8/07.

3. Claims 58-68 are under consideration.

4. Claims 59-68 are objected to because of the following informalities. Said claims recite "Claim 43" whilst they should depend from claim 58. Claim 43 has been cancelled. Appropriate correction is required.

For purposes of examination it will be assumed the claims refer to claim 58 because claim 43 has been cancelled.

5. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 2A-E, 3, 7A-C, 9A-D, 11A-C and 12 A-G are of such poor quality that the data presented is obscured. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

6. The abstract of the disclosure is objected to because it does not disclose the claimed invention (aka the method of claim 58). Correction is required. See MPEP § 608.01(b).

7. Applicant is required to update the status of all US applications disclosed in the instant application.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 58-62,64-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the methods of claims 58-62,64-68. The claims encompass use of in vivo assays and unspecified assays wherein original claim 43 is limited to an in vitro method. Regarding the specification, page 23, the cited passage is limited to an in vitro method wherein OPGbp/ligand binding is measured. Said passage also includes an additional step wherein the compound is measure for agonist or antagonist activity, but there is no description as to how said activity is measured. Regarding claim 62, original claim 43 is limited to a method wherein osteoclast formation is measured in a cell culture.

There is no written description of the scope of the claimed inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

10. Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed method.

The claimed method encompasses use of ODAR protein. The only ODAR protein disclosed in the specification is murine ODAR as per Figure 10. The claims encompass use of any mammalian ODAR including human ODAR. The claims encompass use of ODAR variants, mutants and alleles, yet there is no disclosure of such specific proteins in the specification. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of

The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

11. Claims 58,60,62-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed method.

Regarding claim 58, the preamble of said claim recites that the compound decreases the activity of OPGbp of SEQ. ID. No. 4. However, the actual assay uses OBGbp wherein said OBGbp appears to encompass molecules other than SEQ. ID. No. 4. For example, claim 59 uses a soluble form of SEQ. ID. No. 4 and claim 61 uses a fragment thereof. Therefore, it appears that the method steps of claim 58 encompass use of OPGbp other than that recited in the preamble of said claim. Therefore, the

claimed method encompasses use of osteoprotegerin binding protein (OPGBP) per se. The only OPGBP disclosed in the specification are mouse and human as per Figures 1 and 4. The claims encompass use of any mammalian OPGBP. The claims encompass use of OPGBP variants, mutants and alleles, yet there is no disclosure of such specific proteins in the specification.

Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of

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Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes,

but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

12. Regarding the application of prior art, for the same reasons that claims lack written description as per the reason stated above, they are not entitled to priority to the parent applications for which priority is claimed. Regarding claim 63, there is no support for said claim (or cancelled claim 43) in the parent applications to which priority is claimed. Claim 43 which provides support for claim 63 was filed with the instant application and therefore does not constitute new matter. However, there is no disclosure of said method in the parent applications to which priority is claimed. Regarding the specification, page 23, the cited passage is limited to an in vitro method wherein OPGbp/ligand binding is measured. Said passage also includes an additional step wherein the compound is measure for agonist or antagonist activity, but there is no description as to how said activity is measured.

13. Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter. Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the following matter not disclosed in the prior-filed application. The new matter not supported in the specification is that referred to in paragraphs 12 and 9 of this Office Action.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 58-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle (US Patent 6,316,408) in view of Choi et al. (WO 02/16551).

Boyle teaches OPGbp of SEQ. ID. No. 4 and the various fragments recited in the claims (see columns 7-9). Boyle teaches that compounds that interact with OPGbp can be screened by measuring the binding of said compound to OPGbp and then further characterizing the ability of said compound to decrease OPGbp activity (see column 11, third paragraph). Boyle teach that such compounds can include antibodies (see column 9, penultimate paragraph). Boyle teaches that OPGbp binds to ODAR (see columns 12-15). Boyle et al. do not teach the method of claim 58 using osteoclast formation in vitro or the method of claim 64. Choi et al. disclose in vitro assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said protein (see pages 18-20). Choi et al. also teach that said compounds can also be evaluated in vivo wherein the effect on the test cell is evaluated in vivo (see page 21, second paragraph). Boyle disclose that OPGbp effects osteoclast activity and bone resorption (see column 2, penultimate paragraph). Decreased bone resorption results in increased bone density. It would have been prima facia obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Boyle teaches that compounds that interact with OPGbp can be screened by measuring the binding of said compound to OPGbp and then further characterizing the ability of said compound to decrease OPGbp activity whilst Choi et al. disclose that in vitro and in vivo assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said compound. One of ordinary skill in the art would have been motivated to do the aformentioned because Choi et al. disclose that in vitro and in vivo assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said compound.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RONALD B. SCHWADRON
PRIMARY EXAMINER
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Ron Schwadron, Ph.D.
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